

Thiamethoxam Re-evaluation Study Summary and Review

Sub. No.: 2012-1919

EAD DER No.

PMRA No.: 2365330 (hyperlink)	Study title reference Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Picardie (France), in 2009 Author: Knabe, S. Report Date: 22-JUN-10 Study reference (EFSA locator): S08-01284
MRID No.:	No
GLP:	Yes.
Type of Study:	Semi-field study with honeybees in maize treated with A9700B (thiamethoxam) + A9638A. A9700B is Cruiser 350 FS, which is a relevant EUP for Canada, registered for Wheat, barley, corn, rye, triticale, buckwheat, millet, sorghum, soybeans and beans at 62.5 g ai/ha maximum rate, or 0.25 mg per kernel for corn (up to 100 g ai/100 kg seed). The colonies were kept in the tunnels until the collection of samples has been completed (for at least 5 days).
End-use product tested and rate of application	A9700B (thiamethoxam) (at 350 g/L) and A9638A (fludioxinil at 25 g/L and metalaxyl-M at 10 g/L)
Crop	Treated maize was sown in spring 2008, followed by treated winter barley in autumn 2008, and then followed by untreated alfalfa, <i>Phacelia</i> and oilseed rape in spring 2009.
Plot size	200 m ² tunnels were set-up in each individual crop. The dimensions of each tunnel (covered area) were 40 m long, 5 m wide and 3.5 m high in the centre. The tunnel frames were covered with light plastic gauze (mesh size: approximately 1.5 mm).
Drilling of seeds	Equipment used for drilling treated seed was calibrated prior to use. The manufacturer of the single seed drilling machine for the maize drilling was Monosem. Details of drilling machine is in Appendix I.
Number of replicates	There were 3 tunnels in the treatment plot in each flowering crop and 1 tunnel in the control plot.
Assessment	Residues were analysed the following season. Condition of the colonies and development of bee brood were assessed before the start of the experiment and once after removal of hives. The following parameters were assessed: <ul style="list-style-type: none"> • Colony strength (number of bees, estimation adapted to IMDORF & GERIG, 1999, and IMDORF <i>et al.</i>, 1987) • Presence of a healthy queen (e.g. presence of eggs) • Pollen storage area and area with nectar or honey (estimation adapted to IMDORF & GERIG, 1999, and IMDORF <i>et al.</i>, 1987) • Area containing cells with eggs, larvae and capped cells (estimation adapted to

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	<p>IMDORF & GERIG, 1999, and IMDORF <i>et al.</i>, 1987)</p> <p>At each assessment the comb area containing bees and cells with nectar, pollen, eggs, larvae and capped cells were estimated per comb side. From this the total number of bees and cells containing the brood stages, pollen and nectar on the comb were calculated. This was done for all combs per hive.</p>
Guideline:	<p>This GLP compliant study was conducted in compliance with the European Council Directive 91/414/EEC (1997), IVA (BEUTEL <i>et al.</i> 1992) and OEPP/EPPO Guideline No. 170 (3) (2001).</p>
Deviations:	<p>Deviation No. 1:</p> <p>Concerning: Amendment No. 3 to Study Plan: Page 4; 3.3.5 Condition of the Colonies and Brood Assessments</p> <p>Deviation: No brood assessment was made for hive 3T phac at the end of the field phase.</p> <p>Reason: The colony died during transport to the monitoring site.</p> <p>Impact on study: No data available for hive 3T phac at the 2nd brood assessment.</p> <p>Deviation No. 2:</p> <p>Concerning: Study Plan: Page 6; 3.1 Test Item and Control</p> <p>Deviation: The batch of A9700B used for the maize seed treatment was SSP6A002 instead of SSP7F512.</p> <p>Reason: Change of batch during seed dressing by the sponsor.</p> <p>Impact on study: None.</p> <p>Deviation No. 3:</p> <p>Concerning: Study Plan: Page 8; 3.2.2 Recording of the meteorological Data during Drilling and the entire Growing Period</p> <p>Deviation: No relative air humidity was recorded for the study period except for drilling.</p> <p>Reason: Mistake of the technician.</p> <p>Impact on study: None, the air humidity has no influence on the sampling of forager bees and growth of plants.</p> <p>Deviation No. 4:</p> <p>Concerning: Study Plan: Page 8; 3.2 Drilling and Crop Maintenance Details</p> <p>Deviation: The pesticide history of the field site selected was not available for the two previous cropping seasons before the start of the study.</p> <p>Reason: Information could not be provided by the farmer.</p> <p>Impact on study: None, there were no residues of thiamethoxam or CGA322704 in the soil at the start of the study.</p>
Study Design:	<p>The objective of the study was to determine the magnitude of residues of thiamethoxam (CGA293343) and its metabolite CGA322704 (clothianidin) in crop, soil and honeybee products, followed by use of a flowable concentrate mixture of thiamethoxam as a seed treatment for maize and barley, followed by untreated flowering crops, to evaluate potential exposure to honeybees, <i>Apis mellifera</i> L.</p> <p>Maize pre-treated with the seed treatment A9700B (thiamethoxam) + A9638A was sown in a field plot in the region Picardie, France in spring 2008. The rate of thiamethoxam applied was 76.80 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 71.78 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seed. In</p>

	<p>spring 2009, untreated flowering crops (alfalfa, oilseed rape and <i>Phacelia tanacetifolia</i>) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.</p> <p>In each tunnel one bee colony was placed during the flowering phase. The condition of the colonies and the development of the bee brood were assessed before introduction to the tunnel and once after colonies were moved out of the tunnel. Samples of forager bees, whole plants of all three flowering crop species (oilseed rape, alfalfa and <i>Phacelia tanacetifolia</i>) and soil were collected and sent for analysis of thiamethoxam and its metabolite CGA322704.</p>
Collection of residues? Results as presented by study author.	<p>YES.</p> <p>Soil samples for residue analysis were taken pre-planting of each crop in both the control and test item field plots from the relevant part.</p> <p>Whole plants of all three flowering crop species (oilseed rape, alfalfa and <i>Phacelia tanacetifolia</i>) were collected inside the tunnels on three sampling dates during the experimental period at the time of bee sampling: DAE1 (+2 days), DAE3 (± 2 days) and DAE7 (± 2 days).</p> <p>After set-up of the colonies, forager bees were collected on three sampling days: DAE1(+2 days), DAE3 (± 2 days) and DAE7 (± 2 days).</p> <p><u>Soil:</u></p> <p>Residues in the treated soil samples were between <0.001 mg/kg and 0.024 mg/kg for thiamethoxam and between <0.001 mg/kg and 0.005 mg/kg for CGA322704 (clothianidin). There were no residues found before drilling of maize and before drilling of barley. Residues in the plot seeded with treated seeds increased with each sampling and were at the highest level before the seeding of alfalfa on 02 April 2009 with 0.024 mg/kg of soil. At the seeding of <i>Phacelia tanacetifolia</i> on 20 May 2009 residues were down at 0.009 mg/kg soil for thiamethoxam. No residues of thiamethoxam or CGA322704 above the LOQ were detected in any of the control soil samples.</p> <p><u>Plants:</u></p> <p>Residues in the treated alfalfa plant samples were between 0.002 mg/kg and 0.005 mg/kg for thiamethoxam and between 0.002 mg/kg and 0.005 mg/kg for CGA322704 (clothianidin). No residues of thiamethoxam above the LOQ were detected in the control alfalfa plant sample. Residues of 0.004 mg/kg were detected for CGA322704. This is likely to be interference in the alfalfa matrix, and not contamination of specimens by CGA322704. It was also found in untreated samples of other studies (S08-01279 and S08-01285).</p> <p>No residues for thiamethoxam were detected in the control <i>Phacelia</i> plant samples. Residues were between 0.001 mg/kg and 0.006 mg/kg for thiamethoxam and 0.005 mg/kg and 0.012 mg/kg soil for CGA322704. No residues of thiamethoxam or CGA322704 above the LOQ were detected in the control <i>Phacelia</i> plant samples.</p> <p>Residues in the treated oilseed rape plant samples were between 0.003 mg/kg and</p>

	<p>0.012 mg/kg for thiamethoxam and between 0.004 mg/kg and 0.011 mg/kg for CGA322704. No residues of thiamethoxam and CGA322704 above the LOQ were detected in the control alfalfa plant sample.</p> <p><u>Nectar:</u></p> <p>All of the 36 alfalfa samples planned could be used in the analytical analysis. Residues in the treated alfalfa nectar samples were between <0.0005 mg/kg and 0.0005 mg/kg for thiamethoxam. However, only 2 of the 27 samples from the T tunnels had a residue level above the LOQ with 0.0005 mg/kg. No residues above the LOQ were detected for CGA322704. No residues of thiamethoxam or CGA322704 above the LOQ were detected in any of the control alfalfa nectar samples.</p> <p>All of the 36 <i>Phacelia</i> samples planned could be used in the analytical analysis. Residues in the treated <i>Phacelia</i> nectar samples were between 0.0003 mg/kg and 0.0014 mg/kg for thiamethoxam. Residues were below LOQ (< 0.001 mg/kg) for CGA322704. No residues of thiamethoxam or CGA322704 above the LOQ were detected in any of the control <i>Phacelia</i> nectar samples.</p> <p>33 of the planned 36 oilseed rape samples had a high enough amount of nectar to be used for analytical analysis. Eight of the samples were control samples and the remaining 25 treatment samples. There were samples for each sampling day and each tent but not each sampling in each tent. Residues in the treated summer oilseed rape nectar samples were between <0.0005 mg/kg and 0.0052 mg/kg for thiamethoxam. Residues were detected for CGA322704 with values between <0.001 mg/kg and 0.0023 mg/kg. However, only three samples were showing any values above the LOQ (<0.001). No residues of thiamethoxam or CGA322704 above the LOQ were detected in any of the control summer oilseed rape nectar samples.</p> <p><u>Pollen:</u></p> <p>For alfalfa there was only a very low amount of pollen sampled by the bees. All the pollen from all three sampling dates and tents was just enough for one analysis. Residues of thiamethoxam in the treated alfalfa pollen samples were below the LOQ (<0.001 mg/kg) and for CGA322704 residues were also below the LOQ (<0.001 mg/kg). No residues of thiamethoxam or CGA322704 above the LOQ were detected in the control alfalfa pollen sample.</p> <p>20 of the planned 36 <i>Phacelia</i> samples had a high enough amount of pollen to perform an analysis. One of the samples was a pooled sample from the control tunnels and the remaining 19 treatment samples. There were samples for each sampling day and but not for each tent. Residues in the treated <i>Phacelia</i> pollen samples were between <0.001 mg/kg and 0.001 mg/kg for thiamethoxam and between <0.001 mg/kg and 0.003 mg/kg for CGA322704. No residues of thiamethoxam or CGA322704 above the LOQ were detected in the control <i>Phacelia</i> pollen samples.</p> <p>36 of the planned oilseed rape samples had a high enough amount of pollen to perform an analysis. Residues in the treated summer oilseed rape pollen samples were between 0.004 mg/kg and 0.008 mg/kg for thiamethoxam and between 0.001 mg/kg and 0.003 mg/kg for CGA322704. No residues of thiamethoxam or</p>
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	<p>CGA322704 above the LOQ were detected in any of the control summer oilseed rape pollen samples.</p> <p>The high amount of residues found in individual <i>Phacelia</i> pollen samples and alfalfa pollen samples could not be reanalyzed due to the low amount of pollen available for analysis.</p>
Results of residue analysis as presented by PMRA.	Assessment of residues can be found in PMRA 2425497.
Conclusions (study author) (EAD changes in redink/blueink)	<p><u>Colony and brood assessments</u></p> <p>The strength of the colonies (estimated number of adult bees inside the hive) for all crops was between 6 138 and 20 319 bees per hive before the colonies were moved in the tents. After the colonies were moved out strength was between 9 385 and 17 197 adult bees per hive. One of the hives placed in the <i>Phacelia</i> died during transport from the field. The average numbers in alfalfa and <i>Phacelia</i> increased while the numbers in oilseed rape decreased.</p> <p>The number of eggs in the hives declined from the brood assessment before the study to the time when the hives were assessed after the conduct of the test. Only in one hive of one treatment tunnel in alfalfa were more eggs were found. The number of larvae did not decrease as strongly as the eggs. There were two treatment tunnels in alfalfa and oilseed rape crop where the number of larvae increased between the two brood assessments. In the <i>Phacelia</i> field, numbers of larvae increased only in the control tent. For the cells with capped brood there was a general reduction, but numbers increased in all three flowering crops for one treatment tunnel. This is a result that is expected from standard bee tunnel tests.</p> <p>The mean number of bees measured on June 4/15 during the study was 17403/12802 in the oilseed treatment group and the total number of bees counted in the one control oilseed hive was 20319/14074. The mean number of bees on July 7/22 was 13533/16196 in the <i>Phacelia</i> treatment group and the total number of bees counted in the one <i>Phacelia</i> control hive was 12763/14946. The mean number of bees on July 7/22 was 13906/11637 in the alfalfa treatment group and the total number of bees counted in the one alfalfa control hive was 11074/15195.</p> <p>The mean number of combs containing brood measured on June 4/15 was 6.33/6 in the oilseed treatment group and the total number of combs containing brood was 6/6 in the one oilseed control hive. The mean number of combs containing brood on July 7/22 was 7.33/7.5 in the <i>Phacelia</i> treatment group and the total number of combs containing brood was 7/7 in the one control hive. The mean number of combs containing brood on July 7/22 was 7.33/7 in the alfalfa treatment group and the total number of combs containing brood was 6/7 in the one alfalfa control hive.</p> <p>The mean number of cells containing eggs measured on June 4/15 was 4333/2533 in the oilseed rape treatment and the total number of cells containing eggs was 8200/1600 in the one oilseed control hive. The mean number of cells containing eggs during the study on July 7/22 was 5600/2900 in the <i>Phacelia</i> treatment group and the total number of cells containing eggs was 7800/3800 in the one <i>Phacelia</i> control hive.</p>

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	<p>The mean number of cells containing eggs on July 7/22 was 4467/2333 in the alfalfa treatment groups and the total number of cells containing eggs was 5000/4000 in the one alfalfa control hive.</p> <p>The mean number of cells containing larvae measured on June 4/15 was 5267/4867 in the oilseed treatment group and the total number of cells containing larvae was 8400/3600 in the one oilseed control hive. The mean number of cells containing larvae during the study on July 7/22 was 8867/6200 in the Phacelia treatment group and the total number of cells containing larvae was 5000/9200 in the one Phacelia control hive. The mean number of cells containing larvae on July 7/22 was 6800/5667 in the alfalfa treatment group and the total number of cells containing larvae was 6800/4600 in the one alfalfa control hive.</p> <p>The mean number of cells containing capped brood measured on June 4/15 was 11933/11133 in the oilseed treatment group and the total number of cells containing capped brood was 12600/11800 in the one oilseed control hive. The mean number of cells containing capped brood during the study on July 7/22 was 20067/13733 in the Phacelia treatment group and the total number of cells containing capped brood was 19400/17200 in the one Phacelia control hive. The mean number of cells containing capped brood on July 7/22 was 13200/11133 in the alfalfa treatment group and the total number of cells containing capped brood was 14600/13000 in the one alfalfa control hive.</p> <p>The mean number cells containing nectar measured on June 4/15 was 61067/52067 in the oilseed treatment group and the total number of cells containing nectar was 63000/50200 in the one oilseed control hive. The mean number cells containing nectar on July 7/22 was 35133/32100 in the Phacelia treatment group and the total number of cells containing nectar was 34200/34000 in the one Phacelia control hive. The mean number of cells containing nectar on July 7/22 was 36733/26867 in the alfalfa treatment group and the total number of cells containing nectar was 48000/41200 in the one alfalfa control hive.</p> <p>The mean number of cells containing pollen measured on June 4/15 was 5533/6067 in the oilseed treatment group and the total number of cells containing pollen was 2400/3000 in the one oilseed control hive. The mean number of cells containing pollen on July 7/22 was 10200/14700 in the Phacelia treatment group and the total number of cells containing pollen was 13400/10400 in the one Phacelia control hive. The mean number of cells containing pollen on July 7/22 was 14267/8867 in the alfalfa treatment group and the total number of cells containing pollen was 12800/6400 in the one alfalfa control hive.</p> <p><u>Residues</u> In conclusion low residues of thiamethoxam and CGA322704 (clothianidin) can be found in alfalfa, Phacelia and oilseed rape plant tissue, nectar and pollen, due to carry-over from seed treatment applications made the previous year to spring planted maize and autumn planted barley.</p>
Endpoint(s):	The primary focus of this study was to determine carry-over residues the following season.
Uncertainties	<ul style="list-style-type: none"> Both planted seed treatments on maize (76.80 g ai/ha) and barley (71.78 g

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and notes	<p>ai/ha) were higher when compared to the maximum registered Canadian use rate (62.5 g ai/ha).</p> <ul style="list-style-type: none"> • The bees were introduced to non-treated crops the following year, and thus, the exposure scenario in this study is only evaluating systemic uptake from the previous year's application. • It is uncertain if thiamethoxam would dissipate faster in climatic conditions in France as compared to Canada. • It is unclear if there were enough sampling intervals for brood and colony condition to show development in the hives. An overall colony observation (at one point in time) was conducted. • There is uncertainty surrounding the drilling practice in France in 2008 compared to current drilling practice in Canada. The potential concern for drilling practice would be for dust, which may be relevant (for deposition onto field for carry over to next seasons crops) – but not relevant for dust exposure to foraging bees based on the study design. • The mean number of cells containing pollen on July 13/22 was 5267/5200 in the alfalfa treatment group and the total number of cells containing pollen was 1200/800 in the one alfalfa control hive. The amount of pollen in the control alfalfa hive was significantly lower than the corresponding treatment group. There were also lower pollen, eggs, larvae and capped brood in the alfalfa control hive. Although the amount of pollen was lower, there appeared to be some left at study termination. It is possible that being confined to a tunnel affected the alfalfa control hive (?). • Note: Applying these fungicides to treated seed is a very common (almost ubiquitous) field practice. Without them seed germination may have been severely impacted. • The footnotes in Tables 29 – 34 in this trial report refer to a "Liebefeld unit" that is used for counting number of bees, cells containing eggs, larvae, capped brood, nectar or pollen. The definition of this term is not provided. • The main focus of this study was residue collection.
Criteria	<ul style="list-style-type: none"> • The following criteria for the colonies were guaranteed: • at least 4 brood combs with all brood stages • at least 2 honey and pollen combs • bees are free of symptoms of Nosema and other bee diseases (veterinary certificate of good health)
NOTE	An open container with water was placed into each tunnel. The surface of the water was covered with scraps of cork to prevent the bees from drowning.

Summary Tables of results	see [HYPERLINK \I "_APPENDIX_1- _SUMMARY"]
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EAD Evaluator comments (including acceptability and its use in the risk assessment):

EAD NOTES: This study is considered informative. It is considered 'informative' for PMRA and the information will be used in a line of evidence approach in the risk assessment. Uncertainties and limitations will be outlined. The main focus of the study was the collection of residues from carry over. This study is comparable to the Canadian use pattern since carry-over of neonicotinoid residues can occur after repeated planting of treated seed. In the Resistance Management Recommendation section of seed treatment labels, there is a statement that says "Where possible, rotate the use of CRUISER 350FS Seed Treatment Insecticide or other Group 4 insecticides with different groups that control the same pests in a field." However, this statement is not enforceable.

- *Notes on Tier II acceptability*

- *Acceptable with Tier II trial guidelines*

- *Notes on OEPP/EPPO Guideline No. 170 (3) (2001) being followed*

- *Compliant with this guideline*

EAD summary (for monograph): The objective of the study was to determine the magnitude of residues of thiamethoxam (CGA293343) and its metabolite clothianidin (CGA322704) in crop, soil and honeybee products, followed by use of a flowable concentrate mixture of thiamethoxam as a seed treatment for maize and barley, followed by untreated flowering crops, to evaluate potential exposure to honeybees, *Apis mellifera* L.

Maize pre-treated with the seed treatment A9700B (thiamethoxam) + A9638A was sown in a field plot in the region Picardie, France in spring 2008. The rate of thiamethoxam applied was 76.80 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 71.78 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seed. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and *Phacelia tanacetifolia*) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.

In each tunnel one bee colony was placed during the flowering phase. The condition of the colonies and the development of the bee brood were assessed before introduction to the tunnel and once after colonies were moved out of the tunnel. Samples of forager bees, whole plants of all three flowering crop species (oilseed rape, alfalfa and *Phacelia tanacetifolia*) and soil were collected and sent for analysis of thiamethoxam and its metabolite CGA322704.

Colony and brood assessments

The strength of the colonies (estimated number of adult bees inside the hive) for all crops was between 6 138 and 20 319 bees per hive before the colonies were moved in the tents. After the colonies were moved out strength was between 9 385 and 17 197 adult bees per hive. One of the hives placed in the *Phacelia* died during transport from the field. The average numbers in alfalfa and *Phacelia* increased while the numbers in oilseed rape decreased.

The number of eggs in the hives declined from the brood assessment before the study to the time when the hives were assessed after the conduct of the test. Only in one hive of one treatment tunnel in alfalfa were more eggs found. The number of larvae did not decrease as strongly as the eggs. There were two treatment tunnels in alfalfa and oilseed rape crop where the number of larvae increased between the

two brood assessments. In the *Phacelia* field, numbers of larvae increased only in the control tent. For the cells with capped brood there was a general reduction, but numbers increased in all three flowering crops for one treatment tunnel. This is a result that is expected from standard bee tunnel tests.

The mean number of bees measured on June 4/15 during the study was 17403/12802 in the oilseed treatment group and the total number of bees counted in the one control oilseed hive was 20319/14074. The mean number of bees on July 7/22 was 13533/16196 in the *Phacelia* treatment group and the total number of bees counted in the one *Phacelia* control hive was 12763/14946. The mean number of bees on July 7/22 was 13906/11637 in the alfalfa treatment group and the total number of bees counted in the one alfalfa control hive was 11074/15195.

The mean number of combs containing brood measured on June 4/15 was 6.33/6 in the oilseed treatment group and the total number of combs containing brood was 6/6 in the one oilseed control hive. The mean number of combs containing brood on July 7/22 was 7.33/7.5 in the *Phacelia* treatment group and the total number of combs containing brood was 7/7 in the one control hive. The mean number of combs containing brood on July 7/22 was 7.33/7 in the alfalfa treatment group and the total number of combs containing brood was 6/7 in the one alfalfa control hive.

The mean number of cells containing eggs measured on June 4/15 was 4333/2533 in the oilseed rape treatment and the total number of cells containing eggs was 8200/1600 in the one oilseed control hive. The mean number of cells containing eggs during the study on July 7/22 was 5600/2900 in the *Phacelia* treatment group and the total number of cells containing eggs was 7800/3800 in the one *Phacelia* control hive. The mean number of cells containing eggs on July 7/22 was 4467/2333 in the alfalfa treatment groups and the total number of cells containing eggs was 5000/4000 in the one alfalfa control hive.

The mean number of cells containing larvae measured on June 4/15 was 5267/4867 in the oilseed treatment group and the total number of cells containing larvae was 8400/3600 in the one oilseed control hive. The mean number of cells containing larvae during the study on July 7/22 was 8867/6200 in the *Phacelia* treatment group and the total number of cells containing larvae was 5000/9200 in the one *Phacelia* control hive. The mean number of cells containing larvae on July 7/22 was 6800/5667 in the alfalfa treatment group and the total number of cells containing larvae was 6800/4600 in the one alfalfa control hive.

The mean number of cells containing capped brood measured on June 4/15 was 11933/11133 in the oilseed treatment group and the total number of cells containing capped brood was 12600/11800 in the one oilseed control hive. The mean number of cells containing capped brood during the study on July 7/22 was 20067/13733 in the *Phacelia* treatment group and the total number of cells containing capped brood was 19400/17200 in the one *Phacelia* control hive. The mean number of cells containing capped brood on July 7/22 was 13200/11133 in the alfalfa treatment group and the total number of cells containing capped brood was 14600/13000 in the one alfalfa control hive.

The mean number cells containing nectar measured on June 4/15 was 61067/52067 in the oilseed treatment group and the total number of cells containing nectar was 63000/50200 in the one oilseed control hive. The mean number cells containing nectar on July 7/22 was 35133/32100 in the *Phacelia* treatment group and the total number of cells containing nectar was 34200/34000 in the one *Phacelia* control hive. The mean number of cells containing nectar on July 7/22 was 36733/26867 in the alfalfa treatment group and the total number of cells containing nectar was 48000/41200 in the one alfalfa control hive.

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The mean number of cells containing pollen measured on June 4/15 was 5533/6067 in the oilseed treatment group and the total number of cells containing pollen was 2400/3000 in the one oilseed control hive. The mean number of cells containing pollen on July 7/22 was 10200/14700 in the Phacelia treatment group and the total number of cells containing pollen was 13400/10400 in the one Phacelia control hive. The mean number of cells containing pollen on July 7/22 was 14267/8867 in the alfalfa treatment group and the total number of cells containing pollen was 12800/6400 in the one alfalfa control hive.

Residues

In conclusion low residues of thiamethoxam and CGA322704 (clothianidin) can be found in alfalfa, Phacelia and oilseed rape plant tissue, nectar and pollen, due to carry-over from seed treatment applications made the previous year to spring planted maize and autumn planted barley.

EAD Primary Evaluator (Officer No.): 2044

Date: 6 February 2015

Foreign review comments, if available (state agency):

From EFSA 2012 doc:

No detailed information or conclusions in DER regarding brood effects

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Detailed investigations	
Residues	Following crops, nectar and pollen. Forager bees – honey stomachs and pollen loads
Guttation	No
Following crops	Yes, two treatments: 1. Treated maize 2. Treated and untreated barley Alfalfa, oilseed rape, <i>Phacelia tanacetifolia</i>
Bee brood	Yes
Mortality assessments	No
Sublethal effects	No
Long-term monitoring	No
Dust exposure	No

Matrix	Thiamethoxam mg/kg			metabolite CGA322704 mg/kg		
	LOQ mg/kg	Max	Min	LOQ mg/kg	Max	Min
Soil before seeding of maize	0.001	<LOQ	-	0.001	<LOQ	-
Soil before seeding of winter barley	0.001	<LOQ	-	0.001	<LOQ	-
Soil Before first seeding of oilseed rape	0.001	0.013	-	0.001	0.003	-
Soil Before seeding of alfalfa	0.001	0.024	-	0.001	0.005	-
Soil Before seeding of <i>Phacelia</i>	0.001	0.009	-	0.001	0.003	-
Alfalfa plant	0.001	0.005	<LOQ	0.001	0.005	0.001
<i>Phacelia</i> plant	0.001	0.006	<LOQ	0.001	0.012	<LOQ
Oilseed rape plants	0.001	0.012	<LOQ	0.001	0.011	<LOQ
Alfalfa nectar	0.0005	0.0005	<LOQ	0.001	<LOQ	<LOQ
<i>Phacelia</i> nectar	0.0005	0.014	<LOQ	0.001	<LOQ	<LOQ
Oilseed rape nectar	0.0005	0.0052	<LOQ	0.001	0.0023	<LOQ
Alfalfa bee pollen	0.001	<LOQ	<LOQ	0.001	<LOQ	<LOQ
<i>Phacelia</i> bee pollen	0.001	0.001	<LOQ	0.001	0.003	<LOQ
Oilseed rape bee pollen	0.001	0.008	<LOQ	0.001	0.003	<LOQ

EAD peer review comments (agree/disagree/issues):

The peer review agrees with the conclusions of the primary reviewer.

Thiamethoxam Re-evaluation Study Summary and Review

Sub. No.: 2012-1919

EAD DER No.

EAD Secondary Reviewer (Officer No.): 1183
Date: March 3 2015

Any additional registrant comments, if applicable:

APPENDIX 1- SUMMARY TABLES

Calibration of drilling machine (maize, 15 May 2008)

Run	Distance [m]	Output [no of seeds]
1	1.10	9
2	1.15	10
3	1.22	9
Mean	1.16	9.3

Application data of the treatment T (maize)

Treatment		Test item (T)
Date		15 May 2008
Time		15:10-15:37
Drilling machine		Monosem
Distance between rows		80 cm
Distance in row		13 cm
Dosage		
Seeds/ha (target)		100 000
a.i./ha (target)	[g]	80.36
Amount Seeds/ha (target)	[kg]	28.00
Plot size	[m ²]	9400
Amount Seeds/plot (target)	[kg]	26.32
Amount Seeds/plot (applied)	[kg]	19.66
Seeds/ha (applied)		74 700
Deviation from target	[%]	-25.30
a.i./ha (applied)	[g]	60.03
Environment/Crop		
Temperature	[°C]	18.4
Humidity	[%]	90
Wind speed	[m/s]	5.9
Wind direction		n.a.
Ground cover	[%]	0
Soil temperature in seed depth	[°C]	18.2
Cloud cover	[%]	100
Soil conditions		moist

n.a. = not available

Calibration of drilling machine (barley, 27 November 2008)

Run	Distance [m]	Output [g]
1	10	325
2	10	325
Mean	10	325

Application data of the control C (barley)

Treatment		Control (C)
Date		27 November 2008
Time		15:10-16:00
Drilling machine		n.a.
Distance between rows		15 cm
Distance in row		n.a.
Dosage		
Seeds/ha (target)		2 894 737
a.i./ha (target)	[g]	-
Amount Seeds/ha (target)	[kg]	110.00
Plot size	[m ²]	9600
Amount Seeds/plot (target)	[kg]	105.6
Amount Seeds/plot (applied)	[kg]	116.5
Seeds/ha (applied)		3 193 474
Deviation from target	[%]	+10.32
a.i./ha (applied)	[g]	-
Environment/Crop		
Temperature	[°C]	1
Humidity	[%]	79-80
Wind speed	[m/s]	0
Wind direction		n. a.
Ground cover	[%]	0
Soil temperature in seed depth	[°C]	n. a.
Cloud cover	[%]	100

n.a. = not available

Application data of the treatment T (barley)

Treatment		Test item (T)
Date		27 November 2008
Time		16:10-17:00
Drilling machine		n.a.
Distance between rows		15 cm
Distance in row		n.a.
Dosage		
Seeds/ha (target)		2 894 737
a.i./ha (target)	[g]	73.04
Amount Seeds/ha (target)	[kg]	110.00
Plot size	[m ²]	9000
Amount Seeds/plot (target)	[kg]	99.00
Amount Seeds/plot (applied)	[kg]	113.0
Seeds/ha (applied)		3 304 053
Deviation from target	[%]	+14.14
a.i./ha (applied)	[g]	83.37
Environment/Crop		
Temperature	[°C]	1.0
Humidity	[%]	79-80
Wind speed	[m/s]	0
Wind direction		n.a.
Ground cover	[%]	0
Soil temperature in seed depth	[°C]	n.a.
Cloud cover	[%]	100

n.a. = not available

TABLE 26 Results of the brood assessments in the control Cosr

Colony	Cosr
1st Brood assessment: 04 June 2009	
Total number of bees ¹⁾	20818
Total number of combs	20
Number of combs containing brood	7
Number of cells containing eggs ²⁾	5000
Number of cells containing larvae ²⁾	5600
Number of cells containing capped brood ²⁾	21800
Number of combs containing food	13
Number of cells containing nectar ²⁾	44000
Number of cells containing pollen ²⁾	2800

¹⁾ calculated as sum of Liebefeld units * 125

²⁾ calculated as sum of Liebefeld units * 400

osr = oilseed rape

TABLE 27 Results of the brood assessments in the treatment group Tosr

Colony	1Tosr	2Tosr	3Tosr	Mean	STD
1st Brood assessment: 04 June 2009					
Total number of bees ¹⁾	23318	19883	19069	20757	2255
Total number of combs	20	17	17	18	1.73
Number of combs containing brood	7	6	6	6.33	0.58
Number of cells containing eggs ²⁾	3000	3400	6500	4333	1973
Number of cells containing larvae ²⁾	3400	4200	6400	4667	1553
Number of cells containing capped brood ²⁾	16200	15800	14400	15467	945
Number of combs containing food	16	15	13	14.67	1.53
Number of cells containing nectar ²⁾	59800	49600	41800	50400	9027
Number of cells containing pollen ²⁾	2600	3400	3800	3267	611

¹⁾ calculated as sum of Liebefeld units * 125

²⁾ calculated as sum of Liebefeld units * 400

osr = oilseed rape

STD = Standard deviation

TABLE 28 Results of the brood assessments in the control Cphac

Colony	Cphac
1st Brood assessment: 07 July 2009	
Total number of bees ¹⁾	19200
Total number of combs	20
Number of combs containing brood	9
Number of cells containing eggs ²⁾	5200
Number of cells containing larvae ²⁾	8600
Number of cells containing capped brood ²⁾	21600
Number of combs containing food	18
Number of cells containing nectar ²⁾	39400
Number of cells containing pollen ²⁾	14600
2nd Brood assessment: 22 July 2009	
Total number of bees ¹⁾	25635
Total number of combs	20
Number of combs containing brood	6
Number of cells containing eggs ²⁾	2400
Number of cells containing larvae ²⁾	6200
Number of cells containing capped brood ²⁾	6000
Number of combs containing food	17
Number of cells containing nectar ²⁾	31400
Number of cells containing pollen ²⁾	12200

¹⁾ calculated as sum of Liebefeld units * 125

²⁾ calculated as sum of Liebefeld units * 400

phac = *Phacelia*

TABLE 29 Results of the brood assessments in the treatment group Tphac

Colony	1Tphac	2Tphac	3Tphac	Mean	STD
1st Brood assessment: 07 July 2009					
Total number of bees ¹⁾	13885	11449	16824	14053	2691
Total number of combs	20	20	20	20	0
Number of combs containing brood	8	6	8	7.33	1.15
Number of cells containing eggs ²⁾	3600	3000	5800	4133	1474
Number of cells containing larvae ²⁾	6200	6600	10400	7733	2318
Number of cells containing capped brood ²⁾	22000	17200	21000	20067	2532
Number of combs containing food	19	17	20	18.67	1.53
Number of cells containing nectar ²⁾	49200	42800	38600	43533	5338
Number of cells containing pollen ²⁾	10200	5400	7400	7667	2411
2nd Brood assessment: 22 July 2009					
Total number of bees ¹⁾	22073	18129*	20447	20216	1982
Total number of combs	20	20	20	20	0
Number of combs containing brood	7	6	8	7	1
Number of cells containing eggs ²⁾	4800	2800	4000	3867	1007
Number of cells containing larvae ²⁾	7600	6400	6600	6867	643
Number of cells containing capped brood ²⁾	16000	11000	14200	13733	2532
Number of combs containing food	16	17	15	16	1
Number of cells containing nectar ²⁾	37400	33600	26400	32467	5587
Number of cells containing pollen ²⁾	5600	5600	7600	6267	1155

¹⁾ calculated as sum of Liebfeld units * 125²⁾ calculated as sum of Liebfeld units * 400phac = *Phacelia*

STD = Standard deviation

* Varroa observed

TABLE 30 Results of the brood assessments in the control Calf

Colony	Calf
1st Brood assessment: 13 July 2009	
Total number of bees ¹⁾	13009
Total number of combs	20
Number of combs containing brood	6
Number of cells containing eggs ²⁾	3200
Number of cells containing larvae ²⁾	3000
Number of cells containing capped brood ²⁾	13400
Number of combs containing food	17
Number of cells containing nectar ²⁾	46000
Number of cells containing pollen ²⁾	1200
2nd Brood assessment: 22 July 2009	
Total number of bees ¹⁾	16382
Total number of combs	20
Number of combs containing brood	3
Number of cells containing eggs ²⁾	1400
Number of cells containing larvae ²⁾	400
Number of cells containing capped brood ²⁾	3000
Number of combs containing food	15
Number of cells containing nectar ²⁾	38200
Number of cells containing pollen ²⁾	800

¹⁾ calculated as sum of Liebefeld units * 125

²⁾ calculated as sum of Liebefeld units * 400

alf = alfalfa

TABLE 31 Results of the brood assessments in the test item group Talf

Colony	1Talf	2Talf	3Talf	Mean	STD
1st Brood assessment: 13 July 2009					
Total number of bees ¹⁾	13261	19197	14698	15719	3097
Total number of combs	20	20	20	20	0
Number of combs containing brood	7	5	7	6.33	1.15
Number of cells containing eggs ²⁾	4800	3200	5400	4467	1137
Number of cells containing larvae ²⁾	6000	5800	10200	7333	2485
Number of cells containing capped brood ²⁾	21000	8800	14800	14867	6100
Number of combs containing food	19	19	17	18.33	1.15
Number of cells containing nectar ²⁾	42800	52000	30400	41733	10839
Number of cells containing pollen ²⁾	2000	11000	2800	5267	4981
2nd Brood assessment: 22 July 2009					
Total number of bees ¹⁾	15819	10444	16195*	14153	3217
Total number of combs	20	20	20	20	0
Number of combs containing brood	5	6	6	5.67	0.58
Number of cells containing eggs ²⁾	3600	4600	400	2867	2194
Number of cells containing larvae ²⁾	1200	4800	0	2000	2498
Number of cells containing capped brood ²⁾	7400	9000	9000	8467	924
Number of combs containing food	16	18	15	16.33	1.53
Number of cells containing nectar ²⁾	34200	37400	19800	30467	9375
Number of cells containing pollen ²⁾	1800	11600	2200	5200	5546

¹⁾ calculated as sum of Liebefeld units * 125²⁾ calculated as sum of Liebefeld units * 400

alf = alfalfa

STD = Standard deviation

* Varroa observed